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**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

INTELGENX CORP.,	:	
	:	
	:	
Plaintiff/Counterclaim Defendant,	:	
	:	
v.	:	
	:	
WOCKHARDT BIO, AG, WOCKHARDT	:	
LIMITED and WOCKHARDT USA, LLC	:	
	:	CIVIL ACTION NO. 13-05074 (WJM)
Defendants/Counterclaim Plaintiffs,	:	(MF)
	:	
v.	:	
	:	
EDGEMONT PHARMACEUTICALS, LLC	:	
	:	
Third Party Defendant/Involuntary	:	
Plaintiff.	:	

**AMENDED ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS OF
WOCKHARDT BIO, AG; WOCKHARDT LIMITED; AND WOCKHARDT USA, LLC**

ANSWER TO COMPLAINT

Defendants Wockhardt BIO, AG, Wockhardt Limited and Wockhardt USA, LLC
(collectively “Wockhardt”) by and through its attorneys, answer the Complaint for Patent
Infringement filed by Plaintiff IntelGenx Corp. (“IntelGenx”) as follows.

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Wockhardt denies all allegations in IntelGenx’s
Complaint except those expressly admitted below.

THE NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100 et seq. arising from Wockhardt's filing of an Abbreviated New Drug Application (ANDA) with the United States Food and Drug Administration (FDA) seeking approval to commercially market a generic version of IntelGenx's FORFIVO XL® drug product prior to the expiration of United States Patent No. 7,674,479 (the '479 patent) (the patent-in-suit) owned by IntelGenx.

Answer: This paragraph contains legal conclusions to which no response is required. To the extent any response is necessary, Wockhardt admits that IntelGenx purports to bring this action under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, for infringement of U.S. Patent No. 7, 674,479 ("the '479 patent") related to Wockhardt's ANDA seeking approval to market a generic version of FORFIVO XL®. Wockhardt denies all other allegations in Paragraph 1.

THE PARTIES

2. IntelGenx is a Canadian corporation, having its principal place of business at 6425 Abrams, Ville Saint-Laurent, Quebec H4S 1X9, Canada. IntelGenx is wholly owned by IntelGenx Technologies Corp., which is a publicly traded company and is incorporated in Delaware.

Answer: On information and belief, Wockhardt admits the allegations in Paragraph 2.

3. On information and belief, Wockhardt Limited is a company organized and existing under the laws of India, having a principal place of business at Bandra-Kurla Complex, Bandra East, Mumbai 400 051, India. On information and belief, Wockhardt Limited, itself and through its subsidiaries Wockhardt Bio AG and Wockhardt USA, LLC, is in the business of

making and selling generic pharmaceutical products, which it distributes in the State of New Jersey and throughout the United States.

Answer: Wockhardt admits that Wockhardt Ltd. is a company organized and existing under the laws of India, having a place of business at Wockhardt Towers, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India. Wockhardt admits that the distribution and marketing rights for the generic pharmaceutical products manufactured by Wockhardt are given to Wockhardt Bio Ag, which is currently a wholly-owned subsidiary of Wockhardt. Wockhardt USA LLC is an agent of Wockhardt Bio Ag for distribution of the said generic pharmaceutical products in the USA. Wockhardt does not contest that personal jurisdiction is proper in this judicial district for the purposes of this action only. Wockhardt denies any remaining allegations of Paragraph 3.

4. On information and belief, Wockhardt Bio AG, a wholly-owned subsidiary of Wockhardt Limited, is a company organized and existing under the laws of Switzerland, having a principal place of business at Baarerstrasse 43, 6300 Zug, Switzerland. On information and belief, Wockhardt Bio AG, itself and through Wockhardt USA, LLC, is in the business of making and selling generic pharmaceutical products, which it distributes in the State of New Jersey and throughout the United States.

Answer: Wockhardt admits that Wockhardt USA, LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business at 20 Waterview Blvd., Parsippany, New Jersey. Wockhardt admits that Wockhardt USA, LLC is a subsidiary of Wockhardt EU Operations which, in turn, is a subsidiary of Defendant Wockhardt,

Ltd. Wockhardt does not contest that personal jurisdiction is proper in this judicial district for the purposes of this action only. Wockhardt denies any remaining allegations of Paragraph 4.

5. On information and belief, Wockhardt USA, LLC, a wholly-owned subsidiary of Wockhardt Limited, is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 20 Waterview Boulevard, Parsippany, New Jersey 07054. On information and belief, Wockhardt USA, LLC, with the assistance and/or direction of Wockhardt Bio AG and/or Wockhardt Limited, develops, manufactures, markets, imports, offers to sell, and/or sells generic drug products for sale and use in the State of New Jersey and throughout the United States.

Answer: Wockhardt admits that Wockhardt USA, LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business at 20 Waterview Blvd., Parsippany, New Jersey. The remaining allegations of Paragraph 5 contain legal conclusions to which no answer is required. To the extent an answer is required, Wockhardt does not contest that personal jurisdiction is proper in this judicial district for the purposes of this action only. Wockhardt denies any remaining allegations of Paragraph 5.

6. Upon information and belief, Wockhardt USA, LLC, Wockhardt Bio AG, and Wockhardt Limited act in concert with one another and hold themselves out as an integrated unit for purposes of developing, manufacturing, distributing, marketing, importing, and selling generic drug products throughout the United States, including in this judicial district.

Answer: Paragraph 6 contains legal conclusions to which no answer is required. Wockhardt denies the remaining allegations in Paragraph 6.

7. Upon information and belief, Wockhardt USA, LLC, Wockhardt Bio AG, and Wockhardt Limited acted collaboratively and in concert in the preparation and submission of ANDA No. 205079.

Answer: Paragraph 7 contains legal conclusions to which no answer is required. Wockhardt denies the remaining allegations in Paragraph 7.

8. Upon information and belief, following any FDA approval of ANDA No. 205079, Wockhardt Limited, Wockhardt Bio AG, and Wockhardt USA, LLC will act in concert with one another, and/or with other Wockhardt Limited subsidiaries, to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 205079 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

Answer: Wockhardt admits that it intends to market the drug product disclosed in ANDA No. 205079 in the United States as soon as legally permissible after approval of ANDA No. 205079. Wockhardt denies the remaining allegations in Paragraph 8.

JURISDICTION AND VENUE

9. This Court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331 and 1338 (a), 2201 and 2202.

Answer: Wockhardt admits that this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

Answer: Paragraph 10 states a legal conclusion to which no response is required. To the extent a response is required, Wockhardt concedes to appear before this Court for the purposes of this action only. Wockhardt denies the remaining allegations of Paragraph 10.

11. This Court has personal jurisdiction over Wockhardt USA, LLC because it has availed itself of the legal protections of the State of New Jersey by, among other things, maintaining its principal place of business in Piscataway, New Jersey.

Answer: Paragraph 11 contains legal conclusions to which no answer is required. To the extent an answer is required, Wockhardt does not contest that personal jurisdiction is proper in this judicial district for the purposes of this action only. Wockhardt denies the remaining allegations of Paragraph 11.

12. This Court also has personal jurisdiction over Wockhardt USA, LLC because, among other things, as described above, it manufactures, distributes, markets, and sells generic drug products throughout the United States and within New Jersey. Furthermore, upon information and belief, Wockhardt USA, LLC derives substantial revenue from such conduct in New Jersey. Accordingly, Wockhardt USA, LLC has persistent, systematic and continuous contacts with New Jersey and has therefore purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court in this district.

Answer: Paragraph 12 contains legal conclusions to which no response is required. However, for the purposes of this action only, Wockhardt does not contest that this Court has

personal jurisdiction over Wockhardt. Wockhardt denies the remaining allegations of Paragraph 12.

13. This Court also has personal jurisdiction over Wockhardt USA, LLC because it has availed itself of the legal protections of the State of New Jersey by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of New Jersey (e.g., *Aventis Pharms. Inc. v. Wockhardt Limited.*, C.A. No. 07-5647, Answer and Counterclaims of Defendants Wockhardt Limited and Wockhardt USA, LLC at 3 (D.N.J. June 4, 2010); *Sanofi Aventis Us. LLC v. Wockhardt Limited.*, C.A. No. 10-1471, Answer and Counterclaims of Defendants Wockhardt Limited and Wockhardt USA, LLC at 3-4 (D.N.J. Apr. 22, 2010); *Nautilus Neurosciences, Inc. v. Wockhardt USA, LLC*, C.A. No. 11-1997, Defendants Wockhardt USA, LLC's and Wockhardt Limited's Answer and Counterclaims at 4 (D.N.J. Apr. 29, 2011)).

Answer: Paragraph 13 contains legal conclusions to which no response is required. However, for the purposes of this action only, Wockhardt does not contest that this Court has personal jurisdiction over Wockhardt. Wockhardt denies the remaining allegations of Paragraph 13.

14. This Court also has personal jurisdiction over Wockhardt Limited because, among other things, as described above it manufactures, distributes, markets, and sells generic drug products throughout the United States and within New Jersey. Furthermore, upon information and belief, Wockhardt Limited derives substantial revenue from such conduct in New Jersey. Accordingly, Wockhardt Limited has persistent, systematic and continuous contacts with New

Jersey and therefore purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court in this district.

Answer: Paragraph 14 contains legal conclusions to which no response is required. However, for the purposes of this action only, Wockhardt does not contest that this Court has personal jurisdiction over Wockhardt. Wockhardt denies the remaining allegations of Paragraph 14.

15. This Court also has personal jurisdiction over Wockhardt Limited because it has availed itself of the legal protections of the State of New Jersey by, among other things, creating a subsidiary with its principal places of business in New Jersey (i.e., Wockhardt USA, LLC).

Answer: Paragraph 15 contains legal conclusions to which no response is required. However, for the purposes of this action only, Wockhardt does not contest that this Court has personal jurisdiction over Wockhardt. Wockhardt denies the remaining allegations of Paragraph 15.

16. This Court also has personal jurisdiction over Wockhardt Limited because it has availed itself of the legal protections of the State of New Jersey by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of New Jersey (e.g., *Aventis Pharms. Inc. v. Wockhardt Limited.*, C.A. No. 07-5647, Answer and Counterclaims of Defendants Wockhardt Limited and Wockhardt USA, LLC at 3 (D.N.J. June 4, 2010); *Sanofi Aventis Us. LLC v. Wockhardt Limited.*, C.A. No. 10-1471, Answer and Counterclaims of Defendants Wockhardt Limited and Wockhardt USA, LLC at 3-4 (D.N.J. Apr. 22, 2010); *Nautilus Neurosciences, Inc. v. Wockhardt USA, LLC*, C.A. No.

11-1997, Defendants Wockhardt USA, LLC's and Wockhardt Limited's Answer and Counterclaims at 4 (D.N.J. Apr. 29, 2011)).

Answer: Paragraph 16 contains legal conclusions to which no response is required. However, for the purposes of this action only, Wockhardt does not contest that this Court has personal jurisdiction over Wockhardt. Wockhardt denies the remaining allegations of Paragraph 16.

17. This Court also has personal jurisdiction over Wockhardt Bio AG because, among other things as described above, it manufactures, distributes, markets, and sells generic drug products throughout the United States and within New Jersey. Furthermore, upon information and belief, Wockhardt Bio AG derives substantial revenue from such conduct in New Jersey. Accordingly, Wockhardt Bio AG has persistent, systematic and continuous contacts with New Jersey and therefore purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being hauled into court in this district.

Answer: Paragraph 17 contains legal conclusions to which no response is required. However, for the purposes of this action only, Wockhardt does not contest that this Court has personal jurisdiction over Wockhardt. Wockhardt denies the remaining allegations in Paragraph 17.

THE PATENT-IN SUIT

18. On March 9, 2010, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '479 patent, entitled "Sustained-Release Bupropion and Bupropion/Mecamylamine Tablets" to inventors Horst G. Zerbe and Nadine Paiement. A copy of the '479 patent is attached hereto as Exhibit A.

Answer: Wockhardt admits that the '479 patent is entitled "Sustained-Release Bupropion and Bupropion/Mecamylamine Tablets," that the patent states on its face an issue date of March 9, 2010, and that the patent lists, on its face, Horst G. Zerbe and Nadine Paiement as inventors of the patent. Wockhardt admits that EXHIBIT A purports to be a copy of the '479 patent. Wockhardt denies that the '479 patent was duly and legally issued.

THE FORFIVO™ XL Product

19. IntelGenx was granted approval for its New Drug Application ("NDA") under Section 505(b)(2) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(b)(2), for bupropion hydrochloride 450 mg extended-release tablets (NDA No. 022497), which is sold under the trade name FORFIVO™ XL. Pursuant to the License and Asset Transfer Agreement dated February 3, 2012, IntelGenx transferred the NDA to Edgemont Pharmaceuticals, LLC. The claims of the patent-in-suit cover, inter alia, pharmaceutical compositions containing bupropion hydrochloride (450 mg). IntelGenx owns the patent-in-suit.

Answer: On information and belief, Wockhardt admits that Edgemont is the holder of NDA No. 022497. Wockhardt is without sufficient information to admit or deny the remaining allegations of Paragraph 19.

20. Pursuant to 21 U.S.C. § 355(b) and attendant FDA regulations, '479 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to FORFIVO™ XL.

Answer: Wockhardt admits that the '479 patent is listed in the Orange Book in connection with FORFIVO™ XL. Wockhardt denies the remaining allegations in Paragraph 20.

ACTS GIVING RISE TO THIS SUIT

21. Pursuant to Section 505 of the FFDCA, Wockhardt filed ANDA No. 205079 ("Wockhardt's ANDA") seeking approval to engage in the commercial manufacture, use, sale, offer for sale or importation of bupropion hydrochloride ER 450 mg tablets ("Wockhardt's Proposed Product") before the patent-in-suit expires.

Answer: Wockhardt admits that it submitted ANDA No. 205079 to the FDA under Section 505 of the Federal Food Drug and Cosmetic Act ("FFDCA") seeking approval to engage in the commercial manufacture, use and sale of bupropion HCl 450 mg tablets. Wockhardt denies all other allegations of Paragraph 21.

22. In connection with the filing of its ANDA as described in the preceding paragraph, Wockhardt has provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355G)(2)(A)(vii)(IV) ("Wockhardt's Paragraph IV Certification"), alleging that the claims of the patent-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Wockhardt's ANDA.

Answer: Wockhardt admits the allegations of Paragraph 22.

23. No earlier than July 9, 2013, IntelGenx received written notice of Wockhardt's Paragraph IV Certification ("Wockhardt's Notice Letter") pursuant to 21 U.S.C. § 355G)(2)(B). Wockhardt's Notice Letter alleged that the claims of the patent-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Wockhardt's ANDA. Wockhardt's Notice Letter evinces its intent to seek approval to market Wockhardt's Proposed Product before

the patent-in-suit expire.

Answer: Wockhardt admits that by letter dated July 8, 2013, Wockhardt notified IntelGenx that Wockhardt submitted ANDA No. 205079 to the FDA under section 505(j) of the FFDCA and that its ANDA contains a Paragraph IV certification asserting that the claims of the '479 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Wockhardt's ANDA. Wockhardt denies all other allegations of Paragraph 23.

COUNT I: INFRINGEMENT OF THE '479 PATENT

24. Plaintiff repeats and re-alleges the allegations of paragraphs 1-23 as though fully set forth herein.

Answer: Wockhardt incorporates its answers to Paragraphs 1-23 as if fully set forth herein.

25. Wockhardt, through its submission of its Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of bupropion hydrochloride (450 mg) tablets prior to the expiration of the '479 patent.

Answer: Wockhardt admits that it submitted ANDA No. 205079 to the FDA under Section 505 of the Federal Food Drug and Cosmetic Act ("FFDCA") seeking approval to engage in the commercial manufacture, use and sale of bupropion HCl 450 mg tablets. Wockhardt denies all other allegations of Paragraph 25.

26. Wockhardt's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of bupropion hydrochloride (450 mg) tablets, prior to the expiration of the '479 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

Answer: Paragraph 26 contains legal conclusions to which no response is required. To the extent an answer is required, Wockhardt denies the allegations of Paragraph 26.

27. Wockhardt Limited, Wockhardt Bio AG, and Wockhardt USA, LLC are jointly and severally liable for any infringement of the '479 patent. This is so because, upon information and belief, Wockhardt Limited, Wockhardt Bio AG, and Wockhardt USA, LLC participated in, contributed to, aided and abetted and/or induced the submission of ANDA No. 205079 and its §505Q(2)(A)(vii)(IV) allegations to the FDA. Additionally, upon information and belief, Wockhardt Limited and Wockhardt Bio AG will, without authority, import the Generic Products into the United States for subsequent commercial sale by Wockhardt USA, LLC, Wockhardt Limited and Wockhardt Bio AG under ANDA No. 205079.

Answer: Paragraph 27 contains legal conclusions to which no response is required. To the extent an answer is required, Wockhardt denies the allegations of Paragraph 27.

28. Wockhardt Limited, Wockhardt Bio AG, and Wockhardt USA, LLC's participation in, contributing to, aiding, abetting and/or inducement of the submission of ANDA No. 205079 and its § 505(j)(2)(A)(vii)(IV) allegations regarding the '479 patent to the FDA constitutes infringement under 35 U.S.C. § 271(e)(2)(A). Moreover, if Wockhardt Limited and/or Wockhardt Bio AG import any of the Generic Products into the United States, or induce

or contribute to any such conduct, they would further infringe the '479 patent under 35 U.S.C. § 271(a), (b), and/or (c).

Answer: Paragraph 28 contains legal conclusions to which no response is required. To the extent an answer is required, Wockhardt denies the allegations of Paragraph 28.

29. There is a justiciable controversy between the parties hereto as to the infringement of the '479 patent.

Answer: Paragraph 29 contains legal conclusions to which no response is required. To the extent an answer is required, Wockhardt denies the allegations of Paragraph 29.

30. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will infringe the '479 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States.

Answer: Paragraph 30 contains legal conclusions to which no response is required. To the extent an answer is required, Wockhardt denies the allegations of Paragraph 30.

31. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will induce infringement of the '479 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, upon FDA approval of Wockhardt's ANDA, Wockhardt will intentionally encourage acts of direct infringement with knowledge of the '479 patent and knowledge that its acts are encouraging infringement.

Answer: Paragraph 31 contains legal conclusions to which no response is required.

To the extent an answer is required, Wockhardt denies the allegations of Paragraph 31.

32. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will contributorily infringe the '479 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, Wockhardt has had and continues to have knowledge that Wockhardt's Proposed Product is especially adapted for a use that infringes the '479 patent and that there is no substantial non-infringing use for Wockhardt's Proposed Product.

Answer: Paragraph 32 contains legal conclusions to which no response is required.

To the extent an answer is required, Wockhardt denies the allegations of Paragraph 32.

33. IntelGenx will be substantially and irreparably damaged and harmed if Wockhardt's infringement of the '479 patent is not enjoined.

Answer: Wockhardt denies the allegations of Paragraph 33.

34. IntelGenx does not have an adequate remedy at law.

Answer: Wockhardt denies the allegation of Paragraph 34.

35. This case is an exceptional one, and IntelGenx is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Answer: Wockhardt denies the allegations of Paragraph 35.

PRAYER FOR RELIEF

Wockhardt denies that IntelGenx is entitled to any of the relief requested in its Prayer for Relief and requests that this Court dismiss IntelGenx's claims with prejudice.

WOCKHARDT'S AFFIRMATIVE DEFENSES

Wockhardt asserts the following defenses without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not otherwise expressly admitted.

FIRST AFFIRMATIVE DEFENSE

(No Infringement)

Wockhardt will not infringe, literally, directly, indirectly, contributorily, by way of inducement and/or under the doctrine of equivalents, any valid and enforceable claim of the '479 patent, and if the product that is the subject of ANDA No. 205079 is marketed, Wockhardt will not infringe any valid and enforceable claim of the '479 patent.

SECOND AFFIRMATIVE DEFENSE

(Invalidity)

One or more claims of the '479 patent is invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

THIRD AFFIRMATIVE DEFENSE

(Plaintiff not entitled to exceptional case finding)

Wockhardt's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

FOURTH AFFIRMATIVE DEFENSE

(No costs under 35 U.S.C. § 288)

Plaintiff is barred by 35 U.S.C. § 288 from recovering any costs associated with this suit.

FIFTH AFFIRMATIVE DEFENSE

(Failure to join required party)

Plaintiff failed to join Edgemont Pharmaceuticals, LLC, a required party under Fed. R. Civ. P. 19.

SIXTH AFFIRMATIVE DEFENSE

(Reservation of rights)

Wockhardt reserves all defenses, at law or equity, that may now exist or in the future be available on discovery and further factual investigation in this case.

WOCKHARDT'S COUNTERCLAIMS and THIRD-PARTY CLAIMS

Pursuant to Rule 13, 19, and 20 of the Federal Rules of Civil Procedure, Wockhardt BIO AG, Wockhardt Ltd. and Wockhardt USA, LLC ("Wockhardt"), by way of its attorneys Duane Morris LLP, bring the following Counterclaims against Plaintiff IntelGenx Corp. ("IntelGenx") and Third-Party-Claims against Third party Defendant Edgemont Pharmaceuticals, LLC ("Edgemont"), as follows.

1. Wockhardt repeats and incorporates by reference each of the foregoing paragraphs of Wockhardt's Answer and Affirmative Defenses to the Complaint.
2. This is a counterclaim and Third-Party Claim for Declaratory Judgment of noninfringement and invalidity of one or more claims of United States Patent No. 7,674,479

(“the ‘479 patent”) under 35 U.S.C. § 271(e)(5), 28 U.S.C. §§ 2201 and 2202, and 12 U.S.C. § 355(j). A true and correct copy of the ‘479 patent is attached hereto as EXHIBIT A.

PARTIES

3. Wockhardt USA, LLC is a limited liability company organized under the laws of the State of Delaware, having a principal place of business at 20 Waterview Boulevard, Parsippany, NJ 07054.

4. Wockhardt Ltd. is an Indian company having a principal place of business at Wockhardt Towers, Bandra-Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India.

5. Wockhardt BIO AG is a wholly-owned subsidiary of Wockhardt Ltd., and is organized and existing under the laws of Switzerland, having a principal place of business at Baarerstrasse 43, 6300 Zug, Switzerland. Wockhardt USA LLC is an agent of Wockhardt BIO AG for distribution of generic pharmaceutical products in the USA.

6. On information and belief, IntelGenx is a Canadian corporation, having its principal place of business at 6425 Abrams, Ville Saint-Laurent, Quebec H4S 1X9, Canada. IntelGenx is wholly owned by IntelGenx Technologies Corp., which is a publicly traded company and is incorporated in the State of Delaware.

7. On information and belief, Edgemont is a limited liability company organized under the laws of the State of New Jersey, having its principal place of business at 1250 Capital of Texas Hwy, South, Building 3, Suite 400, Austin Texas 78746.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction over these Counterclaims for Declaratory Judgment pursuant to 35 U.S.C. § 271(e)(5); 28 U.S.C. §§ 1331, 1337(a), 1338,

2201, 2202; and/or 21 U.S.C. § 355(j), based on an actual controversy between Wockhardt and IntelGenx arising under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*

9. This Court has personal jurisdiction over IntelGenx based at least on the filing by IntelGenx of this lawsuit in this jurisdiction.

10. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and 1400(b) based at least on the filing by IntelGenx of this lawsuit in this venue.

11. This Court has jurisdiction over Edgemont based at least on the fact that it has availed itself of the legal protections of the State of New Jersey by, among other things, organizing itself in New Jersey as a New Jersey Limited Liability Company. Additionally, on information and belief, Edgemont markets and sells its FORFIVO™ XL product in New Jersey.

12. As a New Jersey Limited Liability Company, Edgemont is subject to service of process in New Jersey.

13. Joinder of Edgemont to this litigation will not deprive the Court of subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337(a), 1338, 2201, 2202; and/or 21 U.S.C. § 355(j).

14. Edgemont is a necessary party to this litigation.

15. Without including Edgemont in this litigation the Court cannot accord complete relief among Wockhardt and IntelGenx, any decision of this Court with respect to noninfringement and/or invalidity for the '479 patent may prejudice Edgemont, and Wockhardt would be subject to substantial risk of multiple litigations arising out of the same act of filing ANDA No. 205079 with FDA. In addition, the questions of law and fact related to the '479 patent are common to all the parties.

Orange Book Listing of the ‘479 Patent

16. The ‘479 patent, entitled, “Sustained-Release Bupropion and Bupropion/Mecamylamine Tablets,” was issued by the U.S. Patent and Trademark Office on March 9, 2010.

17. On information and belief, IntelGenx is the assignee of the ‘479 patent.

18. On information and belief, Edgemont Pharmaceuticals LLC (“Edgemont”) is the current holder of approved New Drug Application (“NDA”) No. 022497 for bupropion hydrochloride extended release tablets in 450 mg dosage strength. Edgemont sells this drug product under NDA No. 022497 in the United States, including in this district, under the name FORFIVO™ XL.

19. On information and belief, Edgemont is the exclusive licensee of the ‘479 patent.

20. The Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act require NDA holders to disclose to the Food and Drug Administration (“FDA”) the patent numbers and expiration dates of those patents that the holder believes claim the “drug” for which their NDA is submitted or patents covering a “method of using such drug.” 21 U.S.C. § 355(b)(1) and (c)(2).

21. On information and belief, Edgemont caused the FDA to publish the ‘479 patent in the FDA publication, “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”), in connection with NDA No. 022497 for FORFIVO™ XL.

22. By failing to request that the FDA cease listing of the ‘479 patent in the Orange Book, Edgemont represents that claims of the ‘479 patent “could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale of the drug.” 21 U.S.C. § 355(1)(G).

Wockhardt's Abbreviated New Drug Application

23. Wockhardt BIO AG filed Abbreviated New Drug Application (“Wockhardt’s ANDA”) No. 205079 *via* its United States agent Wockhardt USA LLC with the FDA seeking approval to market its proposed 450 mg bupropion HCl extended release tablets. Wockhardt certified to the FDA, pursuant to 21 C.F.R. § 355(j)(2)(A)(vii)(IV) (referred to as a Paragraph IV certification) and 21 C.F.R. § 314.95, that the ‘479 patent is invalid, unenforceable and/or will not be infringed by the manufacture, use, sale and/or offer for sale of Wockhardt’s proposed 450 mg bupropion HCl extended release tablets.

24. In accordance with the requirements of 21 U.S.C. § 355 (j)(2)(B), Wockhardt, through its counsel, sent Plaintiff IntelGenx and NDA holder Edgemont confidential notice letters dated July 8, 2013, stating that it had filed ANDA No. 205079 containing a Paragraph IV certification regarding the ‘479 patent, and offering IntelGenx and Edgemont confidential access to the relevant sections of ANDA No. 205079 pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

The Presence of a Case of Actual Controversy

25. By maintaining the Orange Book listing of the ‘479 patent in connection with the FORFIVO™ XL NDA, Edgemont continues to represent that the claims of the ‘479 patent could reasonably be asserted against anyone making, using or selling a generic 450 mg bupropion HCl extended release tablet without a license from IntelGenx or sublicense from Edgemont.

26. Wockhardt’s Paragraph IV certification states that the claims of the ‘479 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, and/or offer for sale of Wockhardt’s proposed 450 mg bupropion HCl extended release tablets.

27. In response to Wockhardt’s ANDA and Paragraph IV certification against the ‘479 patent, and after accepting Wockhardt’s offer of access to its ANDA, IntelGenx filed this

infringement action under 35 U.S.C. § 271(e)(2)(A), asserting the '479 patent against Wockhardt, thus gaining the exclusionary benefit of an automatic 30-month stay of approval of Wockhardt's ANDA.

28. In discussions between Wockhardt and Edgemont regarding the '479 patent, Edgemont has not been willing to allow Wockhardt to make, use, sell, offer to sell, or import into the United States, the product that is subject of Wockhardt's ANDA No. 205079, without getting a sublicense for the '479 patent from Edgemont, the exclusive licensee of the '479 patent and the NDA-holder for FORFIVO™ XL.

29. Edgemont has not been willing to grant Wockhardt a sublicense for the '479 patent on terms acceptable to Wockhardt, but rather continues to hold the '479 patent rights to prevent Wockhardt from marketing the product that is subject of Wockhardt's ANDA No. 205079.

30. A definite and concrete dispute exists between and among Wockhardt, IntelGenx, and Edgemont, having adverse legal interests susceptible to specific relief through a Declaration of Wockhardt's rights with respect to the '479 patent.

31. There has been, and is now, an actual and justiciable controversy between Wockhardt and IntelGenx and Edgemont as to whether the product disclosed in Wockhardt's ANDA No. 205079 infringes any claim of the '479 patent, and whether any valid, enforceable claim of the '479 patent exists.

32. Wockhardt has not stipulated to or otherwise consented to the validity, infringement or enforceability of any claims of the '479 patent.

33. Wockhardt USA, LLC intends to market the 450 mg bupropion HCl extended release tablets disclosed in ANDA No. 205079 in the United States as soon as legally permissible after approval of Wockhardt's ANDA.

34. A judgment declaring that the claims of the '479 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale and/or offer for sale of Wockhardt's proposed 450 mg bupropion extended-release tablets will remove any independent barriers to competition that may exist by virtue of Edgemont's and IntelGenx's maintenance of the listing of the '479 patent in the Orange Book in connection with NDA No. 022497.

35. In light of all the circumstances, an actual substantial and continuing justiciable controversy having sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between IntelGenx, Edgemont, and Wockhardt as to whether the claims of the '479 patent are invalid, unenforceable, and/or not infringed by Wockhardt and the issuance of an order requiring IntelGenx and Edgemont to immediately request that the FDA delete the '479 patent from the Orange Book listing for NDA No. 022497 for FORFIVO™ XL.

Exceptional Case

36. This case is an exceptional one, and Wockhardt is entitled to an award of its reasonable attorneys' fees and costs under 35 U.S.C. § 285.

FIRST COUNT

(Declaratory Judgment of Noninfringement of U.S. Patent No. 7,674,479)

37. Wockhardt repeats and incorporates by reference each of the foregoing paragraphs of Wockhardt's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

38. This counterclaim and Third-Party Complaint arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between and among IntelGenx, Edgemont, and Wockhardt concerning the infringement of the '479 patent.

39. Wockhardt's manufacture, use, offer for sale, sale and/or importation into the United States of 450 mg bupropion extended release tablets pursuant to ANDA No. 205079 will not infringe any valid claim of the '479 patent.

40. Wockhardt is therefore entitled to a declaration that the manufacture, use, offer for sale, sale and/or importation into the United States of Wockhardt's 450 mg bupropion extended release tablets will not infringe any valid claim of the '479 patent.

SECOND COUNT

(Declaratory Judgment of Invalidity of United States Patent No. 7,764,479)

41. Wockhardt repeats and incorporates by reference each of the foregoing paragraphs of Wockhardt's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

42. This counterclaim and Third-party Complaint arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between and among IntelGenx, Edgemont, and Wockhardt concerning the invalidity of the claims of the '479 patent.

43. The claims of the '479 patent are invalid for failure to comply with the requirements of patentability as specified in 35 U.S.C. §§ 1 *et seq.*, including, without limitation, 35 U.S.C. §§101, 102, 103, 112 and/or 120, and/or based on other judicially-created bases for invalidation.

44. Wockhardt is therefore entitled to a declaration that the claims of the '479 patent are invalid.

WOCKHARDT'S PRAYERS FOR RELIEF

WHEREFORE, Wockhardt prays that the Court enter judgment in its favor and against IntelGenx as follows:

1. Adjudging that Wockhardt has not and will not infringe any valid claim of the '479 patent.
2. Adjudging that no claim of the '479 patent is valid.
3. Enjoining IntelGenx and its agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice hereof from threatening or initiating infringement litigation against Wockhardt or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Wockhardt, or charging them either orally or in writing with infringement of the '479 patent asserted herein against Wockhardt;
4. Enjoining Edgemont and its agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice hereof from threatening or initiating infringement litigation against Wockhardt or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Wockhardt, or charging them

either orally or in writing with infringement of the '479 patent asserted herein against Wockhardt;

5. Granting Wockhardt judgment in its favor on the Complaint;
6. Denying IntelGenx's request for injunctive relief;
7. Dismissing the Complaint with prejudice;
8. Finding this case to be exceptional under 35 U.S.C. § 285 and awarding Wockhardt its costs and reasonable attorneys' fees; and
9. Awarding any other such relief as is just and proper.

Respectfully submitted,

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